

**§ 40.177 What does the second laboratory do with the split specimen when it is tested to reconfirm the presence of a drug or drug metabolite?**

(a) As the laboratory testing the split specimen, you must test the split specimen for the drug(s)/drug metabolite(s) detected in the primary specimen.

(b) You must conduct this test without regard to the cutoff concentrations of § 40.87.

(c) If the test fails to reconfirm the presence of the drug(s)/drug metabolite(s) that were reported positive in the primary specimen, you must conduct validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug(s)/metabolite(s). You should conduct the same validity tests as you would conduct on a primary specimen set forth in § 40.91.

(d) In addition, if the test fails to reconfirm the presence of the drug(s)/drug metabolite(s) reported in the primary specimen, you may send the specimen or an aliquot of it for testing at another HHS-certified laboratory that has the capability to conduct another reconfirmation test.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35972, June 25, 2008]

**§ 40.179 What does the second laboratory do with the split specimen when it is tested to reconfirm an adulterated test result?**

(a) As the laboratory testing the split specimen, you must test the split specimen for the adulterant detected in the primary specimen, using the confirmatory test for the adulterant and using criteria in § 40.95 and confirmatory cutoff levels required by the HHS Mandatory Guidelines.

(b) In addition, if the test fails to reconfirm the adulterant result reported in the primary specimen, you may send the specimen or an aliquot of it for testing at another HHS-certified laboratory that has the capability to conduct another reconfirmation test.

[73 FR 35973, June 25, 2008]

**§ 40.181 What does the second laboratory do with the split specimen when it is tested to reconfirm a substituted test result?**

As the laboratory testing the split specimen, you must test the split specimen using the confirmatory tests for creatinine and specific gravity, and using the confirmatory criteria set forth in § 40.93(b).

[73 FR 35973, June 25, 2008]

**§ 40.183 What information do laboratories report to MROs regarding split specimen results?**

(a) As the laboratory responsible for testing the split specimen, you must report split specimen test results by checking the "Reconfirmed" box and/or the "Failed to Reconfirm" box (Step 5(b)) on Copy 1 of the CCF, as appropriate, and by providing clarifying remarks using current HHS Mandatory Guidelines requirements.

(b) As the laboratory certifying scientist, enter your name, sign, and date the CCF.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35972, June 25, 2008]

**§ 40.185 Through what methods and to whom must a laboratory report split specimen results?**

(a) As the laboratory testing the split specimen, you must report laboratory results directly, and only, to the MRO at his or her place of business. You must not report results to or through the DER or another service agent (e.g., a C/TPA).

(b) You must fax, courier, mail, or electronically transmit a legible image or copy of the fully-completed Copy 1 of the CCF, which has been signed by the certifying scientist.

(c) You must transmit the laboratory result to the MRO immediately, preferably on the same day or next business day as the result is signed and released.

**§ 40.187 What does the MRO do with split specimen laboratory results?**

As the MRO, the split specimen laboratory results you receive will fall into five categories. You must take the following action, as appropriate, when a laboratory reports split specimen results to you.

(a) *Category 1:* The laboratory reconfirmed one or more of the primary specimen results. As the MRO, you must report to the DER and the employee the result(s) that was/were reconfirmed.

(1) In the case of a reconfirmed positive test(s) for drug(s) or drug metabolite(s), the positive is the final result.

(2) In the case of a reconfirmed adulterated or substituted result, the refusal to test is the final result.

(3) In the case of a combination positive and refusal to test results, the final result is both positive and refusal to test.

(b) *Category 2:* The laboratory failed to reconfirm all of the primary specimen results because, as appropriate, drug(s)/drug metabolite(s) were not detected; adulteration criteria were not met; and/or substitution criteria were not met. As the MRO, you must report to the DER and the employee that the test must be cancelled.

(1) As the MRO, you must inform ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(2) In a case where the split failed to reconfirm because the substitution criteria were not met and the split specimen creatinine concentration was equal to or greater than 2mg/dL but less than or equal to 5mg/dL, as the MRO, you must, in addition to step (b)(1) of this paragraph, direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(3) In a case where the split failed to reconfirm and the primary specimen's result was also invalid, direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(c) *Category 3:* The laboratory failed to reconfirm all of the primary specimen results, and also reported that the split specimen was invalid, adulterated, and/or substituted.

(1) In the case where the laboratory failed to reconfirm all of the primary

specimen results and the split was reported as invalid, as the MRO, you must:

(i) Report to the DER and the employee that the test must be cancelled and the reason for the cancellation.

(ii) Direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(iii) Inform ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(2) In the case where the laboratory failed to reconfirm any of the primary specimen results, and the split was reported as adulterated and/or substituted, as the MRO, you must:

(i) Contact the employee and inform the employee that the laboratory has determined that his or her split specimen is adulterated and/or substituted, as appropriate.

(ii) Follow the procedures of § 40.145 to determine if there is a legitimate medical explanation for the laboratory finding of adulteration and/or substitution, as appropriate.

(iii) If you determine that there is a legitimate medical explanation for the adulterated and/or substituted test result, report to the DER and the employee that the test must be cancelled; and inform ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(iv) If you determine that there is not a legitimate medical explanation for the adulterated and/or substituted test result, you must take the following steps:

(A) Report the test to the DER and the employee as a verified refusal to test. Inform the employee that he or she has 72 hours to request a test of the primary specimen to determine if the adulterant found in the split specimen is also present in the primary specimen and/or to determine if the primary specimen meets appropriate substitution criteria.

(B) Except when the request is for a test of the primary specimen and is being made to the laboratory that tested the primary specimen, follow the

procedures of §§ 40.153, 40.171, 40.173, 40.179, 40.181, and 40.185, as appropriate.

(C) As the laboratory that tests the primary specimen to reconfirm the presence of the adulterant found in the split specimen and/or to determine that the primary specimen meets appropriate substitution criteria, report your result to the MRO on a photocopy (faxed, mailed, scanned, couriered) of Copy 1 of the CCF.

(D) If the test of the primary specimen reconfirms the adulteration and/or substitution finding of the split specimen, as the MRO you must report the result as a refusal to test as provided in paragraph (a)(2) of this section.

(E) If the test of the primary specimen fails to reconfirm the adulteration and/or substitution finding of the split specimen, as the MRO you must cancel the test, following procedures in paragraph (b) of this section.

(d) *Category 4:* The laboratory failed to reconfirm one or more but not all of the primary specimen results, and also reported that the split specimen was invalid, adulterated, and/or substituted. As the MRO, in the case where the laboratory reconfirmed one or more of the primary specimen result(s), you must follow procedures in paragraph (a) of this section and:

(1) Report that the split was also reported as being invalid, adulterated, and/or substituted (as appropriate).

(2) Inform the DER to take action only on the reconfirmed result(s).

(e) *Category 5:* The split specimen was not available for testing or there was no split laboratory available to test the specimen. As the MRO, you must:

(1) Report to the DER and the employee that the test must be cancelled and the reason for the cancellation;

(2) Direct the DER to ensure the immediate recollection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection; and

(3) Notify ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(f) For all split specimen results, as the MRO you must in Step 7 of Copy 2 of the CCF:

(1) Report split specimen test results by checking the “Reconfirmed” box and/or the “Failed to Reconfirm” box, or the “Test Cancelled” box, as appropriate.

(2), Enter your name, sign, and date.

(3) Send a legible copy of Copy 2 of the CCF (or a signed and dated letter, see § 40.163) to the employer and keep a copy for your records. Transmit the document as provided in § 40.167.

[73 FR 35973, June 25, 2008, as amended at 75 FR 59108, Sept. 27, 2010]

#### **§ 40.189 Where is other information concerning split specimens found in this regulation?**

You can find more information concerning split specimens in several sections of this part:

§ 40.3—Definition.

§ 40.65—Quantity of split specimen.

§ 40.67—Directly observed test when split specimen is unavailable.

§§ 40.71–40.73—Collection process for split specimens.

§ 40.83—Laboratory accessioning of split specimens.

§ 40.99—Laboratory retention of split specimens.

§ 40.103—Blind split specimens.

§ 40.153—MRO notice to employees on tests of split specimen.

§§ 40.193 and 40.201—MRO actions on insufficient or unavailable split specimens.

APPENDIX D TO PART 40—REPORT FORMAT FOR SPLIT SPECIMEN FAILURE TO RECONFIRM.

### **Subpart I—Problems in Drug Tests**

#### **§ 40.191 What is a refusal to take a DOT drug test, and what are the consequences?**

(a) As an employee, you have refused to take a drug test if you:

(1) Fail to appear for any test (except a pre-employment test) within a reasonable time, as determined by the employer, consistent with applicable DOT agency regulations, after being directed to do so by the employer. This includes the failure of an employee (including an owner-operator) to appear for a test when called by a C/TPA (see § 40.61(a));

(2) *Fail to remain at the testing site until the testing process is complete; Provided, That an employee who leaves the testing site before the testing process*